

REMARKS

Claims 1 and 3-4 are currently under examination in the Application. Reconsideration is respectfully requested in view of the following remarks.

Claims Rejections – 35 U.S.C. § 101, (Utility) and § 112, first paragraph (Enablement)

Claims 1, 3 and 4 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. Claims 1, 3 and 4 also stand rejected under the related § 112, first paragraph, as allegedly lacking enablement due to the alleged lack of utility. In particular, the Action contends that Applicants have not provided evidence regarding the level of expression of the polynucleotide with SEQ ID NO:52 in breast tumor tissue as compared to other tissue. Therefore, the Action asserts that it cannot be concluded that the nucleic acid with SEQ ID NO:52 has any diagnostic value in detecting breast cancer. The Action further asserts that Glucksmann (US 2003/0022334 A1) discloses a sequence which is 99.9% identical to SEQ ID NO:305 which was found to be overexpressed in colon cancer cells. The Action, therefore, concludes that it is not clear that overexpression of the nucleic acid with SEQ ID NO:305 is unique to breast cancer cells. Finally, the Action alleges that since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully traverse this basis of rejection. As noted in Applicants response filed March 10, 2004, the specification as filed clearly states, for example, at page 103, lines 17-25:

cDNA clones isolated in the breast subtractions BS3, BT, 2BT, BC6 and BT-Met, described above, were colony PCR amplified and their mRNA expression levels in breast tumor, normal breast and various other normal tissues were determined using microarray technology. ... The determined cDNA sequences of 131 clones determined to be over-expressed in breast tumor tissue compared to other tissues tested by a visual analysis of the microarray data are provided in SEQ ID NO: 1-35 and 42-137. (emphasis added)

Additionally, the specification notes throughout that over-expression is generally at least two fold greater in tumor tissues as compared to normal tissue. For example, the specification clearly discloses at page 49, lines 2-6:

For example, a polynucleotide may be identified, as described in more detail below, by screening a microarray of cDNAs for tumor-associated expression (*i.e.*, expression that is at least two fold greater in a tumor than in normal tissue, as determined using a representative assay provided herein).

Therefore, Applicants submit that the skilled artisan would readily recognize in view of the teachings in the specification as filed that the polynucleotide set forth in SEQ ID NO:305 is indeed overexpressed in breast tissue as compared to other normal tissues and could be used, for example, in any number of diagnostic settings. Moreover, the specification describes an illustrative utility, as would be readily recognized by the skilled artisan, for those instances where expression is tissue-specific (*e.g.*, breast-specific expression as opposed to breast-tumor specific expression) such as in the case of B854P. See, for example, page 111, lines 6-15.

As further confirmed by the enclosed Declaration of Dr. Davin Dillon, real time PCR analysis showed that the polynucleotide set forth in SEQ ID NO:305 is overexpressed in breast tumor tissue but is not expressed in a panel of other normal tissues. Additionally, as evidenced by the enclosed Declaration, and as would be reasonably expected by the skilled artisan, the protein encoded by the polynucleotide set forth in SEQ ID NO:305 is expressed in breast tumors and normal breast tissue but not in a variety of other normal tissues as shown by immunohistochemical analysis.

Accordingly, Applicants submit that they have shown that the polynucleotide set forth in SEQ ID NO:305 is expressed in breast tissues and therefore, the skilled artisan would readily recognize any number of utilities for the claimed invention, including, for example, as a diagnostic tool for breast cancer. Applicants respectfully submit that the claimed invention is supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility and that the skilled artisan would immediately understand how to make and use the

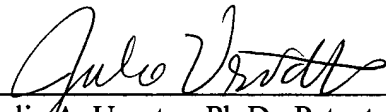
claimed invention. Applicants respectfully request that the rejections under 35 U.S.C. §§ 101 and 112 be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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Enclosure:

Postcard

DILLON DECLARATION WITH FIGURES 1 AND 2

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